

### **REMARKS**

Claims 6-11 constitute the pending claims in the present application. Claims 1-5 were previously cancelled. Claims 6-11 stand rejected. No claims are cancelled or amended herein. A list of the pending claims has been provided for the convenience of the Office.

#### **Telephonic Interview**

Applicants appreciate the time and attention of Examiners Christopher Stone and Brandon Fetterolf during the telephonic interview of January 28, 2010. During the interview, the outstanding obviousness rejection was discussed and the Examiners indicated that they would consider the following remarks when presented in a formal Reply.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office will be addressed below in the order they appear in the prior Office Action.

#### **1. Withdrawal of Prior Rejections of Record**

Applicants note with appreciation the withdrawal of the rejection of claims 6-11 under 35 U.S.C. § 103(a) as allegedly obvious over Kalmar et al. *Exp. Neurol.* 176, 87-97, 2002 (“Kalmar”) in view of Bruening et al. *J. Neurochem.* 72, 694-699, 1999 (“Bruening”).

#### **2. Claim Rejections – 35 § U.S.C. 103 – Claims 6-11**

Claims 6-11 are rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Kalmar. Applicants respectfully traverse the rejection.

The Office contends that Kalmar discloses the compound BRX-220 and that this is tantamount to a disclosure of N-[2-hydroxy-3-(1-piperidinyloxy)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride. The Office further asserts that Kalmar “provides motivation to use the compound in the instantly claimed method ... regardless of a potential lack of structural information about the compound.” See outstanding Office Action at 5.

Applicants respectfully disagree. Pursuant to MPEP 2121(III), “A prior art reference provides an enabling disclosure ... if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention...” Kalmar

does not provide such an enabling disclosure because this reference does not describe in any detail the chemical structure of BRX-220, and no reference has been made of record that identifies the chemical structure of BRX-220. Instead, Kalmar merely recites the uninformative name “BRX-220,” which is insufficient: “[T]he mere naming of a compound in a reference, without more, cannot constitute a description of the compound.” MPEP 2121.02 citing *In re Hoeksema*, 399 F.2d 269 (CCPA 1968). Without the information about the structure of BRX-220, one of ordinary skill would not have known what compound to use in the claimed method, i.e., would not have known to select and use N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride out of the infinite number of compounds that Kalmar describes as “a potent analogue of Bimoclomol.” See Kalmar at 87. Without knowledge as to what compound to use, one of ordinary skill would certainly have faced undue experimentation in making and testing all “analogue[s] of Bimoclomol,” and such undue experimentation is a hallmark of lack of enablement: “[M]ere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation.” MPEP 2121.01 citing *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

Furthermore, because the reference does not disclose the structural information, one of ordinary skill would not have known how to make BRX-220 based on a reading of Kalmar or any other art of record, and so Kalmar is also non-enabling for this additional reason. See MPEP 2121.02(I) entitled “ONE OF ORDINARY SKILL IN THE ART MUST BE ABLE TO MAKE OR SYNTHESIZE.”

Importantly, at the time of filing the present application, BRX-220 was proprietary and not available to the public. Applicants have filed herewith a Declaration Under 35 U.S.C. § 1.132 of Linda Greensmith, a co-inventor of the present application, the lead author of Kalmar and the principle investigator of the experiments conducted therein. As averred in Professor Greensmith’s declaration, BRX-220 and its chemical structure were not available to the public at the priority date of the present application or at Kalmar’s publication date. Accordingly, one of ordinary skill could not have obtained BRX-220 to derive its structure or to use this compound in

the claimed method. Without access to BRX-220 or its structure, the teachings of Kalmar did not enable one of ordinary skill in the art to practice the claimed methods.

Lastly, without access to the identity of BRX-220, Kalmar does not teach or suggest all the elements of the present claims because it does not teach or suggest the use of N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride.

Accordingly, for the above reasons, Kalmar is non-enabling for making and using -[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride and thus non-enabling for the claimed method. Moreover, Kalmar does not teach or suggest all the elements of the present claims. Hence, a *prima facie* case of obviousness has not been established, and Applicants request reconsideration and withdrawal of the rejection.


### **CONCLUSION**

In view of the above remarks and amendments, Applicants submit that the pending application is in condition for allowance. The Examiner may address any questions raised by this submission to the undersigned at (212) 596-9000.

Applicants believe no fee is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 06-1075, under Order No. 004049-0018-101 from which the undersigned is authorized to draw.

Dated: January 28, 2010

Respectfully submitted,

By   
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